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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/580,797 05/30/00 IWEN

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DANN DORFMAN HERRELL & SKILLMAN
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PHILADELPHIA PA 19103-2307

EXAMINER

GOLDBERG, J

ART UNIT

PAPER NUMBER

1655

DATE MAILED:

07/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/580,797

Applicant(s)

IWEN ET AL.

Examiner

Jeanine A Enewold Goldberg

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1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-18 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1, 15-18, drawn to a universal primer set for amplification of a target DNA sequence associated with pathogenic strains of fungi and kits containing the universal primers, classified in class 536, subclass 24.33.
 - II. Claims 2-5, drawn to a method of determining whether one or more fungal species selected from the group of fungal species is present in a sample of fungi, classified in class 435, subclass 6.
 - III. Claims 6, 11, drawn to an oligonucleotide sequence specific for *Penicillium* spp. comprising SEQ ID NO: 25 and an oligonucleotide sequence specific for *Penicillium marnefeii* comprising SEQ ID NO: 30, classified in class 536, subclass 24.3.
 - IV. Claim 7, drawn to an oligonucleotide sequence specific for *Malbranchia* spp. comprising SEQ ID NO: 26, classified in class 536, subclass 24.3.
 - V. Claim 8, drawn to an oligonucleotide sequence specific for *Arthrogrothilus* spp. comprising SEQ ID NO: 27, classified in class 536, subclass 24.3.
 - VI. Claim 9, drawn to an oligonucleotide sequence specific for *Cylindrocarpon destructans* comprising SEQ ID NO: 28, classified in class 536, subclass 24.3.

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- VII. Claim 10, drawn to an oligonucleotide sequence specific for *Sporothrix schenckii* comprising SEQ ID NO: 29, classified in class 536, subclass 24.3.
- VIII. Claim 12, drawn to an oligonucleotide sequence specific for *Coccidioides immitis* comprising SEQ ID NO: 31, classified in class 536, subclass 24.3.
- IX. Claims 13, 14, drawn to an oligonucleotide sequence specific for *Candida tropicalis* comprising SEQ ID NO: 32, and an oligonucleotides specific for *Candida parapsilosis* comprising SEQ ID NO: 33, classified in class 536, subclass 24.3.

2. Further Restriction of Group II-- Upon election of Group II, directed to methods, applicant is required to elect a single genus of fungi for detection. The claim is drawn to a method of determining whether one fungal species is present in a sample. This method is distinct from the method of determining whether all of the fungal species presented are present in a sample. The examiner does not deem it a burden to search a single genus of organisms. The art necessary for a search of *Aspergillus* species is not coextensive of art necessary for a search of *Candida* species.

3. Further, if Group I is elected, applicant may select an additional nucleic acid selected from SEQ ID NO: 3-33 as recited in Claim 18, since it appears that Claim 18 is a kit which contains SEQ ID NO: 1-2 and one additional sequence. If applicant elects

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one of the nucleic acids from Groups III- IX, the examiner will rejoin that group with Group I.

4. The inventions are distinct, each from the other because of the following reasons:

A) Inventions II and (I, III, IV, V, VI, VII, VIII, IX) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the universal primers may be used in a method for detecting all of the fungal species, for detecting the presence of a fungal species, for detecting which fungal species is present. The universal primers are nucleic acids which may be used as adapters. The oligonucleotides which are specific for each fungal species may be used in methods aside from determining whether one or more fungal species is present in a sample. For example, the oligonucleotides may be used in methods for determining similarity between two or more species, classification and even as adapters.

B) The inventions of Groups I, III, IV, V, VI, VII, VIII, IX are patentably distinct products. The products are all directed to distinct nucleic acids. The universal primers of SEQ ID NO: 1-2 are distinct from the genus/species specific primers. The genus specific and species specific oligonucleotides are distinct since they are used to identify

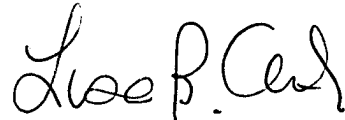
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number is (703) 306-5817. The examiner can normally be reached Monday-Thursday from 7:00AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jeanine Enewold Goldberg
June 28, 2001



LISA B. ARTHUR
PRIMARY EXAMINER
GROUP 1800 1600